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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,461	09/27/2000	Arne Staby	5784.210-US	6001
7590 11/19/2003			EXAMINER	
Carol E Rozek			KAM, CHIH MIN	
Novo Nordisk of North America Inc			ART UNIT	
Suite 6400			PAPER NUMBER	
405 Lexington Avenue			1653	
New York, NY 10174-6401			DATE MAILED: 11/19/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/671,461	STABY, ARNE	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are ~~allowed~~ *free of art*.
- 6) ☒ Claim(s) 2,6 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/522,694.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 2, 4, 6 and 11-15 are pending.

Applicants' amendment filed on July 22, 2003 is acknowledged. Applicants' response has been fully considered. Claims 2, 4, 6 and 11-14 have been amended, and a new claim 15 has been added. Thus, claims 2, 4, 6 and 11-15 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claim 6 under 35 U.S.C. 112, second paragraph as being indefinite, regarding the term "and/or" or "if necessary", is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 4 of the amendment filed July 22, 2003.

Claim Rejections - 35 USC § 102

3. The previous rejection of claims 2, 6, 11, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Lile *et al.* (U. S. Patent 5,606,031), is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 4-5 of the amendment filed July 22, 2003.
4. The previous rejection of claims 2, 6 and 11-14 under 35 U.S.C. 102(b) as being anticipated by Jorgensen *et al.* (US Patent 3,907,676), is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 4-5 of the amendment filed July 22, 2003.

Claim Rejections - 35 USC § 103

5. The previous rejection of claims 2, 4, 6, 11, 13 and 14 under 35 U.S.C. 103(a) as being unpatentable over Lile *et al.* (U. S. Patent 5,606,031) in view of Binz *et al.* (U. S. Patent 6,113,911), is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 5-6 of the amendment filed July 22, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 11, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 6 and 15 are indefinite because the claim depends from a cancelled claim, claim 1.

8. Claims 11 and 12 are indefinite because of the use of the term "derivatives thereof". The term "derivatives thereof" renders the claim indefinite, it is not clear what compound the derivative is, and how different the derivative is from the parent compound.

In response, applicants indicate that the term "vira" has been deleted from claim 11; "FFR" stands for Phe-Phe-Arg, and "FFR-Factor VIIa" has been found clear and cited in claim 4 of U. S. Patent 6,451,987; and "derivatives thereof" has been defined in the specification (page 17, lines 7-10) as a peptide in which one or more of the amino acid residues of the parent peptide have been chemically modified, and one skilled in the art would know what the phrase means. The response has been fully considered, however, the argument is not fully persuasive regarding

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“derivatives thereof” because neither the specification nor the claim indicates what modification has been carried out on the peptide, and what residues are modified, thus, it is not clear what structures the derivatives have. Regarding “vira” and “FFR-Factor VIIa”, the argument is persuasive, thus the rejection is withdrawn.

9. Claim 15 is indefinite because of the use of the term “B28IsoAsp insulin”, it is not clear what IsoAsp is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 2, 6, 11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Korc *et al.* (US 2003/0103980 A1, priority date October 16, 1998).

Korc *et al.* teach GAG-containing forms of glypican-1 and syndecan-1 were purified by anion exchange chromatograph on DEAE-Sepharcel equilibrated in buffer A (50 mM Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100) (paragraphs [0019] and [0068], Fig. 5). Cell lysates containing glypican-1 or syndecan-1 in buffer B (50 mM Tris-HCl, pH 8.0, 0.15 M NaCl, 0.1% triton X-100, 1mM EDTA, 1 µg/ml pepstatin A, 1 mM PMSF) were loaded onto columns, and columns were eluted stepwise with buffer A, buffer C (50 mM Tris-HCl, pH 8.0, 0.25 M NaCl, 0.1% triton X-100), buffer D (50 mM Tris-HCl, pH 8.0, 6 M urea, 0.25 M NaCl, 0.1% triton X-

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100), and buffer E (50 mM sodium formate, pH 3.5, 0.2 M NaCl, 6 M urea, 0.1% triton X-100). After restoring the pH with 50 mM Tris-HCl, pH 8.0, 0.1% triton X-100, glypican-1 or syndecan-1 was eluted from the column with buffer F (50 mM Tris-HCl, pH 8.0, 0.75 M NaCl, 0.1% triton X-100) (claims 2, 11 and 14). The eluted material was diluted five fold with 50 mM Tris-HCl, pH 8.0, 0.1% triton X-100, concentrated, and clarified by filtration, and samples were then resuspended in buffer B and analyzed by immunoblotting (claim 6). The concentration of urea in the buffer is 6 M, which corresponds to the ratio of 1:1.8 of urea to water (claim 13). Since the peptide of glypican-1 or syndecan-1 is still bound to the anion exchange column when the column is eluted with buffers D and E containing 6 M urea, it would be expected that the impurities be eluted from the column using buffers D and E containing 6 M urea because these impurities have lower negative charges and less affinity toward the positively charged resin than the peptide (e.g., glypican-1).

Conclusion

11. Claims 2, 6, 11-15 are rejected, and it appears claim 4 is free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CM/K*
Patent Examiner

November 17, 2003


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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